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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,469	11/07/2001	Vadim Bichko	0342/IH395US1	7244
7590 12/17/2004 DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,469

Applicant(s)

BICHKO, VADIM

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5-12 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,10,11 and 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,6,9,12 and 23 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07/20/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/24/2004 has been entered. An Office Action on RCE follows.

Response to Amendment

This is a response to the amendment, paper No. 18, filed 06/23/01. Claims 1, 3-4 and 13-14 have been canceled. Claims 2, 5-12, and 15-19 have been amended. New claim 23 has been added. Claims 2, 5-12, and 15-23 are pending. Claims 7-8, 10-11 and 15-22 are withdrawn from consideration; Claims 2, 5-10, 12 and 23 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

1. Claim 23 is objected to because of the following informalities: In step (iii) of claim 23 after "transferring", the recitation of "of" should be deleted due to the grammatical mistake. Appropriate correction is required.

New ground Rejections:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. The claim 2 is vague in that it uses a relative term of "derived". Since the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "derived" has many interpretations, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore the claim is considered as indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 5, 6, 12, 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Bartenschlager et al. (US Patent No. 6, 630,343B1).

5. The claimed invention is drawn to an isolated nucleic acid molecule and a host cell comprising same nucleic acid molecule encoding a replication competent recombinant hepatitis C virus genome. The said recombinant HCV genome comprising at least one mutation has a sequence that is not more than 99.9% identical and is at least 95% identical to the sequence of HCVI377/NS3-3'UTR genome (SEQ ID NO: 1). The said recombinant HCV nucleic acid molecule can be transfected into the Huh-7 hepatocyte cell line and replicates efficiently without reducing the growth of said cell line by more than 10-folds.

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6. Bartenschlager et al. disclose several isolated recombinant HCV replication competent clones (See Fig. 10 and lines 22-64 on col. 17) isolated from Huh-7 cell line transfected with a in vitro transcripts of the modified HCV subgenomic constructs recombinant HCV-RNA construct: I377/NS3-3' and I389/NS3-3'. Some of these clones have a sequence that is 99.9% to 99.5% identical to the SEQ ID NO:1. For example, a clone has a nucleic acid sequence of SEQ ID NO: 7 that is just 99.9% identical to the SEQ ID NO: 1. A clone with a sequence of SEQ ID NO: 6, or SEQ ID NO:16 or SEQ ID NO: 28 is 99.4% identical to the SEQ ID NO:1. A clone with sequence of SEQ ID NO: 22 is 95% identical to the SEQ ID NO: 1. Bartenschlager et al. also teach a method for culturing the Huh-7 cell line transfected with those molecules. The conditions for culturing those transfected cells comprise adding the antibiotics selection marker G418 at 1 mg/ml and culturing the cells for up to 5 weeks (See example 2 on col. 21-22). Bartenschlager et al. further disclose that while most clones died during this procedure, and final yields only 9 cell clones.

7. With respect to art rejections above, please note that the patentability of a product does not depend upon its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product may have been made by a different process. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) - see, e.g., MPEP 2113. In the instant case, while the prior art does not teach the some detail process of making the claimed nucleic acid construct, such as to transfer the G418 resistant Huh-7 cells and passaging them about 1-2 time a week for about at least two week etc. this procedure of making the product does not add anymore patentable weight or make the claimed nucleic acid molecule any patentable distinct from that of prior art because the nucleic acid molecule disclosed by the prior art has a same molecular structure of claimed nucleic acid molecule. Therefore, the claims are anticipated by the cited prior art.

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Conclusion

Claim 9 is free of art rejection. However, it is not in the condition for allowance because it depends on the rejection claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao Qun Li M. D.

12-06-2004